

Active Ingredient	Suggested Reference From EURD list	PSUR submission Frequency	DLP	Submission date
Lubiprostone	Previously listed in the EURD list	1 year	8/29/2022	11/7/2022
Colestimide	Colesevelam	3 years	3/10/2021	6/8/2021
Daclatasvir	Sofosbuvir	1 year	12/5/2022	2/13/2023
Limaprost	Previously listed in the EURD list	13 years	1/1/2025	4/1/2025
Mitiglinide	Previously listed in the EURD list	13 years	1/1/2025	4/1/2025
Dalfampridine	Fampridine	3 years	1/21/2023	4/21/2023
Omeprazole + Sodium bi-carbonate	Omeprazole	5 years	4/15/2022	7/14/2022
Bupivacaine Hydrochloride + Fentanyl (injection)	Fentanyl (transdermal patches, solution for injection -nationally authorised product only)	3 years	4/30/2022	7/29/2022
Edaravone	Japan only	1 year	12/12/2022	3/12/2023
Loxoprofen	Ibuprofen	3 years	2/18/2023	5/19/2023
Vilazodone	Trazodone	13 years	10/15/2025	1/13/2026
Gentamicin + Miconazole + Mometasone	Mometasone	3 years	5/22/2023	8/20/2023
Finerenone	Spironolactone	3 years	3/8/2024	6/6/2024
Moxifloxacin HCL+ Dexamethasone (Ophthalmic)	Levofloxacin + Dexamethasone (ocular use)	1 year	6/12/2022	8/21/2023
Alcaftadine (Ophthalmic)	As the Innovator + FDA only	1 year	7/27/2022	10/5/2022
Carboxymethyl Cellulose + Glycerin (Ophthalmic)	Carmellose (eye preparation)	13 years	11/30/2025	2/28/2026
Dexamethasone + Chlorpheniramine	Dexamethasone + Diphenhydramine hydrochloride	13 years	1/1/2025	4/1/2025
Gatifloxacin sesquihydrate (Ophthalmic)	Ofloxacin (Topical use)	3 years	4/16/2024	7/15/2024
Gemifloxacin	Levofloxacin (intravenous and oral use)	3 years	10/1/2023	12/30/2023
Minodronic acid	Risedronate (Japan only)	1 year	5/1/2022	7/10/2022
Rebamipide	Previously listed in the EURD list	13 years	1/1/2025	4/1/2025
Guaifenesin + Oxomemazine + Carbocisteine	Carbocisteine	13 years	9/14/2025	12/13/2025
Butenafine	Terbinafine	5 years	9/30/2022	12/29/2022
Retigabine	Previously listed in the EURD list	1 year	9/28/2021	12/7/2021
Ferrous sulphate + Folic acid + Riboflavine + Pyridoxine HCl + Zinc sulfate + Nicotinamide + Ascorbic acid +Thiamine	Ascorbic acid + Biotin + Cyanocobalamin + Folic acid + Nicotinamide + Pantothenic acid + Pyridoxine hydrochloride + Riboflavin + Thiamine	10 years	9/27/2027	12/26/2027
Neomycin sulfate + Nystatin + Triamcinolone acetonide + Gramicidin	Neomycin sulfate + Nystatin + Triamcinolone acetonide	13 years	1/1/2025	4/1/2025
Aluminium hydroxide gel + Magnesium hydroxide + Oxethazaine	Aluminium hydroxide gel + Dimeticone + Magnesium hydroxide	13 years	1/1/2025	4/1/2025
Glycerin + Carboxymethylcellulose + Sodium Hyaluronate	Glycerol	13 years	1/1/2025	4/1/2025
Ascorbic acid + Zinc	Ascorbic acid	13 years	2/25/2025	5/26/2025
Pipazethate	Non reference	1 year	5/1/2022	7/10/2022
Dexamethasone phosphate + Moxifloxacin	Moxifloxacin (Ophthalmic)	5 years	5/31/2026	8/29/2026
Favipravir	Remdesivir	6 months	5/6/2022	7/15/2022
Artesunate + Sulfamethoxypyrazine + Pyrimethamine	Artesunate	6 months	6/22/2022	8/31/2022
Daclatasvir	Sofosbuvir	1 year	12/5/2022	2/13/2023
Naphazoline HCL + Pheniramine maleate	Naphazoline	12 years	7/31/2024	10/29/2024
Sulphamethoxazole + Trimethoprim + light Kaolin + Pectin	Sulphamethoxazole + Trimethoprim	8 years	3/31/2027	6/29/2027
Aluminium hydroxide gel + Magnesium hydroxide + Simeticone	Aluminium oxide + Magnesium hydroxide + Simeticone	13 years	1/1/2025	4/1/2025
Ethanolamine Oleic acid	Ethanolamine	13 years	1/1/2025	4/1/2025
Metformin Hydrochloride + Repaglinide	Metformin	3 years	1/4/2024	6/30/2024
Paracetamol + Pseudoephedrine + Diphenhydramine	Paracetamol + Pseudoephedrine + Chlorpheniramine	13 years	1/1/2025	4/1/2025
Metoclopramide + Pyridoxine	Metoclopramide	3 years	11/17/2024	2/15/2025

Levodopa + Entacapone	<b>Carbidopa + Entacapone + levodopa</b>	<b>3 years</b>	<b>10/7/2024</b>	<b>1/15/2025</b>
Pemiroloast	<b>Japan only</b>	<b>1 year</b>	<b>4/30/2022</b>	<b>7/29/2022</b>
Tolmetin sodium	<b>Aceclofenac</b>	<b>3 years</b>	<b>3/31/2023</b>	<b>6/29/2023</b>
Sulfacetamide + Prednisolone	<b>Prednisolone</b>	<b>13 years</b>	<b>7/13/2025</b>	<b>10/11/2023</b>
Eperisone	<b>Tolperisone</b>	<b>3 years</b>	<b>6/1/2022</b>	<b>8/30/2022</b>
Phenylephrine Hydrochloride + Hypromellose (Ophthalmic Solution)	<b>Phenylephrine (Ophthalmic formulations)</b>	<b>5 years</b>	<b>1/1/2025</b>	<b>4/1/2025</b>
Carbazochrome + Troxerutin	<b>Carbazochrome</b>	<b>13 years</b>	<b>3/19/2025</b>	<b>6/17/2025</b>
Meclofenoxate	<b>Japan only</b>	<b>1 year</b>	<b>4/30/2022</b>	<b>7/9/2022</b>
Loratidine + Paracetamol + Pseudoephedrine	<b>Paracetamol + Pseudoephedrine</b>	<b>5 years</b>	<b>6/28/2023</b>	<b>9/26/2023</b>
Ursodeoxycholic acid + Silymarin	<b>Ursodeoxycholic acid, tauroursodeoxycholic acid</b>	<b>10 years</b>	<b>11/30/2026</b>	<b>2/28/2027</b>
Nitazoxanide	<b>FDA only</b>	<b>1 year</b>	<b>7/29/2022</b>	<b>10/7/2022</b>
Imeglimin Hydrochloride	<b>Japan only</b>	<b>1 year</b>	<b>4/30/2022</b>	<b>7/9/2022</b>
Molnupiravir	<b>Newly authorized</b>	<b>6 months</b>	<b>12/18/2021</b>	<b>2/26/2022</b>
Vitamin B1 + Vitamin B2 + Vitamin B6 + Nicotinamide + Dexpanthenol	<b>Caffeine + Dexpanthenol+ Nicotinamide + Pyridoxine + Riboflavine + Thiamin</b>	<b>13 years</b>	<b>1/1/2025</b>	<b>4/1/2025</b>
Vitamin B1 + Vitamin B2 + Vitamin B6 + Vitamin B12 + Nicotinamide + Calcium D-pantothenate + Ascorbic acid + Folic acid + Calcium phosphate + Ferrous sulphate + Potassium Iodide + Manganese sulphate + Potassium sulphate + Zinc sulphate	<b>Ascorbic acid + Biotin + Cyanocobalamin + Folic acid + Nicotinamide + Pantothenic acid + Pyridoxine hydrochloride + Riboflavin + Thiamine</b>	<b>10 years</b>	<b>9/27/2027</b>	<b>12/26/2027</b>
Guaifensine + Terpine + cineol + sodium benzoate	<b>Guaifensine/ herbal extract</b>	<b>13 years</b>	<b>1/1/2025</b>	<b>4/1/2025</b>
Cefdinir	<b>Cefotaxime</b>	<b>3 years</b>	<b>12/18/2024</b>	<b>3/18/2025</b>
Sodium Chloride + Sodium Bicarbonate + Borax	<b>Sodium Chloride</b>	<b>13 years</b>	<b>11/24/2025</b>	<b>2/22/2026</b>
Benzoic acid + Salicylic acid (Topical)	<b>Salicylic acid (Topical use)</b>	<b>13 years</b>	<b>4/25/2025</b>	<b>7/24/2025</b>
Paracetamol + Pamabrom	<b>Paracetamol + Orphenadrine citrate</b>	<b>13 years</b>	<b>1/1/2025</b>	<b>4/1/2025</b>
Chlorphenoxamine hydrochloride + Caffeine	<b>Chlorphenoxamine hydrochloride</b>	<b>5 years</b>	<b>5/17/2023</b>	<b>8/15/2023</b>
Phenylephrine Hydrochloride + Cyclopentolate Hydrochloride (Ophthalmic Solution)	<b>Phenylephrine Hydrochloride (Ophthalmic)</b>	<b>5 years</b>	<b>1/1/2025</b>	<b>4/1/2025</b>
Amoxicillin + Flucloxacillin	<b>Amoxicillin</b>	<b>5 years</b>	<b>3/7/2022</b>	<b>6/5/2022</b>
Acephylline piperazine	<b>Piperazine</b>	<b>13 years</b>	<b>1/1/2025</b>	<b>4/1/2025</b>
Vonoprazan	<b>Japan only</b>	<b>1 year</b>	<b>8/23/2022</b>	<b>11/1/2022</b>
Doripenem	<b>Meropenem</b>	<b>13 years</b>	<b>8/31/2034</b>	<b>11/29/2034</b>
Armodafinil	<b>Modafinil</b>	<b>1 year</b>	<b>8/31/2021</b>	<b>11/9/2021</b>
Clidinium Bromide + Chlordiazepoxide	<b>Acidinium Bromide</b>	<b>1 year</b>	<b>7/20/2022</b>	<b>9/28/2022</b>
Oxytetracycline hydrochloride + Polymyxin b	<b>Hydrocortisone acetate + Oxytetracycline hydrochloride + Polymyxin b</b>	<b>13 years</b>	<b>1/1/2025</b>	<b>4/1/2025</b>
Telmisartan + Amlodipine + Hydrochlorothiazide	<b>Olmесartan + Amlodipine + Hydrochlorothiazide</b>	<b>5 years</b>	<b>4/24/2022</b>	<b>7/23/2022</b>
Chlorzoxazone + Paracetamol	<b>Chlorzoxazone</b>	<b>13 years</b>	<b>6/28/2025</b>	<b>9/26/2025</b>
Silver sulfadiazine + Chlorhexidine Digluconate	<b>Silver sulfadiazine</b>	<b>5 years</b>	<b>9/15/2025</b>	<b>12/14/2025</b>
Dexpanthenol + Dexamethasone	<b>Dexpanthenol + Hydrocortisone</b>	<b>13 years</b>	<b>1/1/2025</b>	<b>4/1/2025</b>
Dextromethorphan + Chlorpheniramine	<b>Dextromethorphan</b>	<b>3 years</b>	<b>11/1/2024</b>	<b>1/30/2025</b>
Diloxanide + Metronidazole	<b>Non reference</b>	<b>1 year</b>	<b>10/25/2022</b>	<b>1/3/2023</b>
Cyanocobalamin -Tannin complex in Aluminium monostearate	<b>Cyanocobalamin</b>	<b>13 years</b>	<b>2/22/2025</b>	<b>5/23/2025</b>
Magnesium hydroxide + Light Liquid Paraffin	<b>Magnesium hydroxide</b>	<b>5 years</b>	<b>10/31/2026</b>	<b>1/29/2027</b>
Nonoxynol-9	<b>Non reference</b>	<b>1 year</b>	<b>5/1/2022</b>	<b>7/10/2022</b>